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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/691,405	10/17/2000	Steven R. Binder	2558B-063700US	3942

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TOWNSEND AND TOWNSEND AND CREW, LLP  
TWO EMBARCADERO CENTER  
EIGHTH FLOOR  
SAN FRANCISCO, CA 94111-3834

EXAMINER

ALLEN, MARIANNE P

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/691,405		BINDER ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Marianne P. Allen		1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5-10 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-10, 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Claims 19-20 have been newly added. Claims 1-2, 5-10, and 12-20 are under consideration.

#### ***Claim Rejections - 35 USC § 112***

Claims 1-2, 5-10, and 12-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has substantively amended claims 1 and 17 and introduced new claims 19-20.

Claim 1 now recites “wherein each stored reference data set is associated with none, one or more of said systemic autoimmune diseases.” The specification discloses a reference data set associated with none or one of the named systemic autoimmune diseases but does not appear to contemplate reference data sets associated with two or more of the named systemic autoimmune diseases. For example, there is no disclosure of testing biological samples from a patient known to have both Sjogren’s syndrome and CREST (or any other combinations).

Claim 17 recites “has a specific association with one of said systemic autoimmune diseases.” Basis is stated to be on page 4, lines 24-26. However, this portion of the specification does not disclose nor contemplate the concept of a specific association nor what level of association this might reflect.

Claim 19 recites that the values for the reference data set and the test data set are each determined simultaneously. Basis is stated to be on page 3. However, this portion of the

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specification indicates that autoantibody levels from a particular sample may be determined simultaneously. It does not speak to multiple data sets being determined simultaneously.

Claim 20 recites wherein the set of tests are performed substantially simultaneously. Basis is stated to be on page 3. This portion of the specification does not disclose nor contemplate the concept of “substantially simultaneously.” It is not known what time frame would meet this limitation.

**Should this new matter rejection be overcome, the enablement rejection set forth in the prior Office action would still apply to the claims for the reasons of record.**

Note that only claims 7 and 8 specify particular antibodies to test. As written, one could practice the invention by testing for autoantibodies to microtubule organizing center (MTOC) (associated with rheumatoid arthritis) and MOG (associated with multiple sclerosis) in biological samples from a test subject and for the plurality of subjects known to have one or none of the named diseases. Executing the method by quantitating these autoantibodies would tell you nothing about whether the test subject had any of the diseases named in the preamble of the claim as these autoantibodies are not known to be associated with SLE, scleroderma, Sjogren’s syndrome, polymyositis, dermatomyositis, CREST and connective tissue disease.

Applicant’s arguments indicate that while the claims as written are directed to a method of identifying the particular autoimmune disease that a test subject is suffering from, the true intent of the claims is a data mining method to discover those autoantibodies, if any, that may be statistically associated with the named autoimmune diseases and be capable of discriminating between them. That is, from the haystack of all autoantibodies (known and unknown, associated

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with a named autoimmune disease or not), one of ordinary skill in the art is to find the needle or collection of needles that will reveal the autoantibody profile diagnostic for a particular condition, if any such profile should exist. This is an invitation to experiment as set forth in the prior Office actions. While the specification and claims set forth a general research plan for a problem that would have been known to be of interest (and complex) to those of ordinary skill in the art, the specification has not provided a solution nor sufficient guidance to enable one to find a solution. Again, the specification has not exemplified any method for identification within the claims nor provided guidance on the how to adapt the known statistical techniques for solving the problem of identifying systemic autoimmune disease in a subject. One of ordinary skill in the art would be required to make independent decisions and judgments on how to apply the statistical techniques, what parameters to use or change, assumptions to make, and so forth. Any model developed must be tested and validated. This is not considered to be routine experimentation. It requires one of ordinary skill in the art practicing the invention to use inventive skill to develop applicant's claimed method. Again, the specification provides no training set with the information required to produce statistically derived decisions with respect to systemic autoimmune diseases. The reference data must be collected and evaluated, assumptions as to what specific data will be used must be made and the composition of the training set and test sets and so forth must be determined. The specification does not exemplify any implementation of the claimed methods and provides no specific guidance for doing so.

None of applicant's arguments are persuasive with respect to enablement of the claimed methods.

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***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*Marianne P. Allen*  
Marianne P. Allen  
Primary Examiner 5/11/04  
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mpa